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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,211	06/18/2001	Robertson Scott Alan	PC10743A	3787

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/884,211	Alan, et al.
Examiner	**Art Unit**
Michael Brannock	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 22, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-69* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 24, drawn to polynucleotides and methods of producing a polypeptide, classified in class 536, subclass 23.5.

II. Claims 21, 22, 25, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 23 and 69, as claim 69 relates to an antibody, drawn to antibodies, classified in class 350, subclass 388.22.

IV. Claims 26-28, drawn to methods of detecting a polynucleotide, classified in class 435, subclass 6.

V. Claims 29-37, drawn to methods of identifying binding partners, agonists and antagonists of a polypeptide, classified in class 435, subclass 7.2.

VI. Claims 38-40, 43, 47, 48, 50, 52-54, 57, 63-68, as the claims relate to an agonist of a MC4R, drawn to methods of administering an MC4R agonist, classification dependent on the chemical identity of the agonist.

VII. Claims 38, 39, 41, 42, 44, 47-50, 55-62, 65-68, as the claims relate to an antagonist of a MC4R, drawn to methods of administering an MC4R antagonist, classification dependent on the chemical identity of the antagonist.

VIII. Claims 45 and 46, drawn to transgenic animals, classified in class 435, subclass 800.

IX. Claim 69, drawn to an MC4R ligand, classification dependent on the chemical nature of the ligand.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-III and IX are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in the gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods. Although, the protein of Group II can be used to identify the binding partner (i.e. ligand) of Group IX, the protein could

also be used to produce the antibody of Group III. Although, the DNA of Group I can be used to produce the protein of Group II which can be used to identify the binding partner of Group IX, the DNA could also be used to as a diagnostic probe. The binding partners of Group IX are distinct from the protein and from the DNA because the binding partners could be obtained from sources other than those employing the protein of Group II or the DNA of Group I, such as from commercial vendors. Furthermore, the antibody of Group III is distinct from the non-antibody binding partner of Group IX, because one is not required for the use of the other.

The polynucleotides of Group I and the transgenic animal of Group VIII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a probe for diagnostic purposes or to produce the polypeptides of Group II and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. The transgenic animal is

unrelated to the products of Groups II, III and IX because one is not required for the use of the other.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV-VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires a hybridization assay, which is not required by any of the other groups. Group V requires an in vitro assay, which is not required by any of the other groups. Group VI requires the administration an MC4R agonist to an animal, which is not required by any of the other groups. Group VII requires the administration an MC4R antagonist, which is not required of any of the other groups.

The polynucleotides of Group I are related to the methods of Groups IV and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups IV and V because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV and V are materially and functionally distinct each other. Furthermore, the polynucleotides of Group I and the

methods of Groups VI and VII are patentably distinct because one is not required for the use of the other.

The polypeptides of Group II are related to the methods of Group V as product and process of use. In the instant case the polypeptides of Group I are patentably distinct from the methods of Group V because the polypeptides of be used in ways that are materially and functionally different than the methods of Group I, such as to produce the antibody of Group III for immunohistological diagnostic purposes. Furthermore, the polypeptides of Group II and the method of Groups IV, VI, and VII are patentably distinct because one is not required for the use of the other.

The antibodies of Group III are related to the methods of Groups IV-VI as product and process of use. In the instant case the antibodies of Group III are patentably distinct from each of the methods of Groups IV-VI because the antibodies can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV-VI are materially and functionally distinct from the others. Furthermore, the antibodies of Group III and the method of Group IV are patentably distinct because one is not required for the use of the other.

The kit of Group IX is related to the methods of Groups IV-VI as product and process of use. In the instant case the kit of Group IX is patentably distinct from the methods of Groups IV-VI because the products of the kit can be used in ways that are materially and functionally different then each of the methods of either of Groups IV-VI, because, as discussed above, each

of the methods of Groups IV-VI are materially and functionally distinct from the others. Furthermore, the kit of Group IX and the methods of Group IV are patentably distinct because one is not required for the use of the other. Similarly, the transgenic animal of Group VIII and the methods of Groups IV-VII are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to methods comprising the administration of the following patentably distinct species: polynucleotides of SEQ ID NO: 1, polynucleotides of SEQ ID NO: 3, polypeptides of SEQ ID NO: 2, and polypeptides SEQ ID NO: 4.

The above identified species are materially and functionally distinct molecules and are patentably distinct, the use of one not being required for the use of any other. Further, a search of methods of administering ligands of one species could not be relied upon, solely, to provide art that is anticipatory or would render obvious any other.

4. Applicant is required under 35 U.S.C. 121 to elect a single group from Groups I-IX and also a single disclosed species for prosecution on the merits to which the claims shall be

restricted. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Further, if Applicant elects for prosecution either Group III, VI, VII, or IX, applicant is additionally required to elect a species of appetite-related or metabolic disorder, such species being defined as that involving a single identifiable patient population, e.g. crowding stress, diabetes, cancer, renal failure, etc, each disorder having distinct etiologies and requiring divergent treatment steps and goals. Claim 69 is generic to pharmaceutical compositions. The term "pharmaceutical composition" implicitly requires that the composition be useful for some form of treatment of a disorder or condition. A search of one disorder could not be relied upon to, solely, to provide art that is anticipatory or would render obvious the treatment of any other disorder, and to search all species of disorders would be burdensome.

If Applicant elects either Group III, VI, VII, or IX, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of disorder or condition, such disorder or condition being that which there is a recognized single patient population, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, clams 38-44, 47-54, 57-59, 61-69 appear to be generic to methods and compositions for the treatment of a disorder or condition.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

February 10, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600